

Handwritten initials: AB



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,658	08/13/1999	Luisa Iruela-Arispe	1448.1070006	2817

22195 7590 12/30/2004
HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Handwritten mark: 17

Office Action Summary

Application No.

09/373,658

Applicant(s)

IRUELA-ARISPE ET AL.

Examiner

Karen A Canella

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 24-37, 46-56, 59 and 86-88 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 24-37, 46-56, 59- is/are allowed.
- 6) ☐ Claim(s) 86-88 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-23-38-45, 57, 58 and 60-85 have been canceled. Claims 86-88 have been added. Claims 24-37, 46-56, 59 and 86-88 are pending and under consideration.
2. Text of Title 35, U.S. Code not found in this action can be found in a previous action.
3. Claims 86-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) As drawn to new matter

Newly added claims 86 and 87 are drawn to a polynucleotide minimally comprising a fragment consisting of at least 30 and 50 consecutive nucleotides of SEQ ID NO:125, respectively. Claim 88 is drawn to a polynucleotide minimally comprising a fragment consisting of at least 20 consecutive nucleotides of SEQ ID NO:126. Applicant asserts that support for this amendment is found in 08/845,496 which is incorporated by reference. Upon review of these citations it is noted that page 8 of the '496 application states that "representative fragments of the invention include, for example, fragments from about amino acid number 1-20, 21-40, 41-60, 61-80, 81-100 and 101 to the end of the ITGL-TSP polypeptide. Each of the contemplated polypeptide fragments would correspond to 60 nucleotide residues. This is not adequate support for the instant claims. On page 14 of the '496 application it is states that "probes" will generally comprise 15, 30 or 50 nucleotides and such probes will range between 30 and 50 nucleotides. this is not adequate support for the instant claims to polynucleotides which minimally comprise 20, 30 or 50 nucleotides because the claimed nucleotides are not limited in size to 50 nucleotides as those described in the '496 application. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus of polynucleotides.

(B)As drawn to inadequate written description

The instant claims are drawn to polynucleotides which minimally comprise 30 and 50 consecutive nucleotides of SEQ ID NO:125 and 20 consecutive nucleotides of SEQ ID NO:126.

Art Unit: 1642

The claims encompass a genus of polynucleotide which can include many polynucleotides which differ in structure from SEQ ID NO:125 and 126. The genus is highly variant because it includes structural variants which minimally comprise the required number of nucleotides and functional variants which differ in the activity of the polynucleotides. The description of SEQ ID NO:125 and 126 fails to describe the claimed genus because the genus comprises members which differ widely in structure and function from instant SEQ ID NO:125 and 126. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus of polynucleotides.

4. All other rejections and objections as set forth in the previous Office action are withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D

12/27/2004


KARENA. CANELLA PH.D
PRIMARY EXAMINER